UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,492	12/04/2001	Rango Dietrich	24826	6447

34375 7590 03/12/2003

NATH & ASSOCIATES PLLC
1030 FIFTEENTH STREET, N.W.
SIXTH FLOOR
WASHINGTON, DC 20005

EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/980,492	Applicant(s) DIETRICH ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 January 2003 (paper no.7)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5-7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Priority documents filed 12/04/01, the Preliminary Amendment filed 12/04/01, the IDS filed 02/25/02, the IDS filed 09/11/02 and the Supplemental IDS filed 01/10/03.

Claims 1-20 are pending. Claims 1-20 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 9, the phrase "*such as*" in lines 2 and 3, renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

It is suggested that the phrase "*such as*" be either positively recited or deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 and 9-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Akiyama *et al.* (US Pat. No. 5,948,773; collectively, "Akiyama").

Akiyama discloses a pharmaceutical formulation comprising an antibacterial substance and/or an anti-ulcer substance, in that the anti-ulcer substance is a proton pump inhibitor, wherein at least either one of them is formulated into a gastrointestinal mucosa-adherent solid preparation, which comprises a matrix containing a combination mixture of fatty acid esters, lipids and viscogenic agents, whereby lipids include saturated fatty acids or salts thereof, higher alcohols – cetyl alcohol, stearyl alcohol, fatty acid glycerol esters (mono-, di- or triglycerides), waxes, hydrocarbons – paraffin, microcrystalline wax and phospholipids) in combination with pharmaceutically acceptable excipients (see reference column 2, line 16 through col. 3, line 67); (col. 9, line 20 through col. 13, line 59).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama *et al.* (US Pat. No. 5,948,773; collectively, "Akiyama") in view of Linder *et al.* (US Pat. No. 6,328,993; collectively, "Linder").

Akiyama, as discussed above, teaches a pharmaceutical formulation comprising an antibacterial substance and/or an anti-ulcer substance, in that the anti-ulcer substance is a proton pump inhibitor, wherein at least either one of them is formulated into a gastrointestinal mucosa-adherent solid preparation, which comprises a matrix containing a combination mixture of fatty acid esters, lipids and viscogenic agents, whereby lipids include saturated fatty acids or salts thereof, higher alcohols – cetyl

alcohol, stearyl alcohol, fatty acid glycerol esters (mono-, di- or triglycerides), waxes, hydrocarbons – paraffin, microcrystalline wax and phospholipids) in combination with pharmaceutically acceptable excipients (see reference column 2, line 16 through col. 3, line 67); (col. 9, line 20 through col. 13, line 59).

The anti-ulcer substance includes H2 blockers and proton pump inhibitors, wherein proton pump inhibitors are preferred. The proton pump inhibitors include benzimidazole compounds such as lansoprazole, timoprazole, omeprazole and pantoprazole, for example (col. 3, lines 55-67; col. 9, lines 20-34). The salt of a benzimadole compound id preferably used as a physiologically acceptable salt. Physiologically acceptable salts include salts with *inorganic bases*, salts with organic bases and salts with basic amino acids (col. 9, lines 39-49).

The formulation of the invention is used as (1) a combination of an anti-ulcer substance and a gastrointestinal mucosa-adherent solid preparation containing an antibacterial substance, (2) a combination of an antibacterial substance and a gastrointestinal mucosa-adherent solid preparation containing an anti-ulcer substance, (3) a gastrointestinal mucosa-adherent solid preparation containing both an antibacterial substance and an anti-ulcer substance, or (4) a combination of a gastrointestinal mucosa-adherent solid preparation containing an antibacterial substance and a gastrointestinal mucosa-adherent solid preparation containing an anti-ulcer substance. The combination of an anti-ulcer substance and a gastrointestinal mucosa-adherent solid preparation containing an antibacterial substance is preferred (col. 9, lines 53-67).

Akiyama teaches that the matrix containing a polyglyerol fatty acid ester may also incorporate a lipid. The lipid is a water-soluble substance that serves to control the dissolution rate of active ingredients, exemplified by the previously mentioned lipids (col. 13, lines 12-16).

The solid preparation may incorporate additives that include excipients, such as lactose, corn starch, talc, crystalline cellulose; binders, such as sucrose, methyl cellulose, polyvinylypyrrolidone, etc; disintegrating agents, wetting agents, stabilizers and the like (col. 13, lines 28-52).

Example compositions for oral administration include tablets, pills, granules, powders, capsules, syrups, emulsions and suspensions. These compositions are produced by known methods, using lactose, starch, sucrose, magnesium stearate and other substances as carriers or excipients (col. 17, lines 25-29).

Akiyama teaches the inclusion of lipids in the formulation, but is deficient only in the sense that he does not explicitly teach the selected sterols in the formulation.

Linder teaches an administration form comprising acid-labile proton pump inhibitors comprising the use of at least one sterol, whereby suitable sterols include phytosterols, such as ergosterol, stigmasterol, sitosterol, brassicasterol and campesterol and zoosterols, such as cholesterol and lanosterol or mixtures thereof (see reference column 2, line 45 through column 4, line 15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Linder within the teachings of

Akiyama because Linder explicitly teaches that various sterols can be used in the proton pump inhibiting composition and Akiyama teaches also teaches that various lipids can be formulated in the anti-ulcer composition. The expected result would be an improved proton pump inhibiting composition for the effective treatment of disease, as similarly desired by the applicant.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
March 10, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY/CENTER 1600